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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/154,274	09/16/1998	ZOLTMAN G. TURI	BTG-5001	6727

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08/13/2003

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EXAMINER

THALER, MICHAEL H

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/154,274

Applicant(s)

TURI, ZOLTMAN G.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 28-51, 53-72, 74-96 and 98-201 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 33-37, 48, 58-60, 64, 65, 79-83, 92, 93, 103-105, 109, 110, 161, 173-175, 181-189 and 195-201 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 30 June 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims allowed are 1-26,28-32,38-47,49-51,53-57,61-63,66-72,74-78,84-91,94-96,98-102,106-108,111-160,162-172,176-180 and 190-194.

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2003 has been entered.

Claims 36, 37, 82 and 83 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims fail to further limit the subject matter of a previous claim because every blood vessel is a tubular structure and every blood vessel is body tissue.

Claim 161 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the original disclosure for the limitation for the step of deforming the blood vessel. Note that the term "deformed" is defined in Patent No. 5,556,414 as being subject to

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a force greater than the elastic limit of the material (col. 8, lines 46-50). Although the original disclosure indicates that graft 100 is deformed, it does not indicate that the blood vessel is deformed.

Claims 33-37, 48, 58-60, 64, 65, 79-83, 92, 93, 103-105, 109, 110, 173-175, 181-189 and 195-201 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buirge et al. (5,693,085). Buirge et al. show expandable member 10 and sleeve 13 formed of "collagen material" adjacent to the interior surface of the expandable member 10. The term "collagen material" is defined quite broadly in the Buirge et al. patent as including the materials disclosed in U. S. Patent Numbers 4,902,508 and 5,281,422 among others (col. 9, line 64 to col. 10, line 9). Patent No. 4,902,508 to Badylak et al. discloses that the graft may be formed of tissue as indicated by the term "tissue graft" in col. 2, lines 42 and 48, "tissue layers" in col. 2, lines 67-68 and "collagenous connective tissue" in col. 3, line 9, for example. Also, Patent No. 5,281,422 to Badylak et al. discloses that the graft may be formed of tissue as indicated in col. 1, lines 51 to col. 2, line 44, for example. Thus, Buirge et al. disclose tissue disposed adjacent to the interior surface of the expandable member as claimed. Alternatively, it would have been obvious that Buirge et al. "collagen material" includes tissue for the reasons set forth above. As to claims 33, 79, 173 and 187,

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Buirge et al., in figure 7, disclose tissue 12, 13, which, when secured to the stent and each other constitute tissue which has a length (along the interior of the stent and along the exterior of the stent) about twice as long the expandable member. As to claims 34-37, 58-60, 80-83, 103-105, 174, 175, 182-184, 188, 189 and 197-199, Buirge et al., from col. 10, line 58 to col. 11, line 4, disclose tissue 12 extending beyond the ends of the expandable member 10 and folded back over respective ends of the expandable member to meet about midway (when one cuff 16 is sutured to the other as described from col. 10, line 67 to col. 11, line 1 but not shown in figure 14). Alternatively, it would have been obvious that, in this embodiment not shown in the drawings, cuffs 16 are longer than shown in figure 14 and meet since tissues which are sutured to each other generally meet. As to claims 48 and 181, Buirge et al. disclose that the stent may be delivered and expanded by the device disclosed in US Patent No. 5,195,984 to Schatz (col. 2, lines 14-18). Schatz discloses a delivery sheath 89 as part of the delivery apparatus. Therefore, Buirge et al. disclose a delivery sheath as claimed. As to claims 64, 92, 185, 195 and 200, Buirge et al. disclose welding the tissue to the expandable member (col. 11, lines 2-4). As to claims 65, 93, 186, 196 and 201, Buirge et al. disclose fixing a first portion of the tissue (one cuff 16) to a second portion of tissue (the other cuff 16) from col. 10, line 58 to col. 11, line 4.

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Claims 1-26, 28-32, 38-47, 49-51, 53-57, 61-63, 66-72, 74-78, 84-91, 94-96, 98-102, 106-108, 111-160, 162-172, 176-180 and 190-194 are allowed.

Claim 161 is free of any rejection based upon the prior art of record.


Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
August 6, 2003


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731